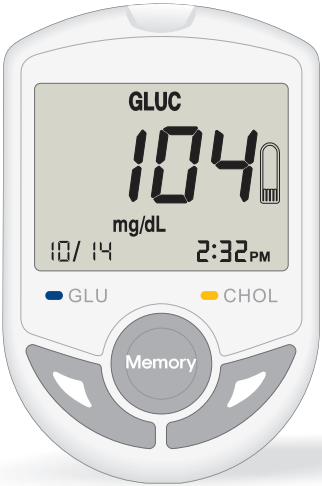

Model: TBG-460GC

Blood Glucose / Cholesterol 2 in 1 Monitoring System

User's Manual

2012/03/12 Rev.00

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Chapter 1 TBG-460GC Monitoring System

1.1 Introduction

Thank you for choosing Blood Glucose / Cholesterol Monitoring System. Please read the "User's Manual" for your convenient and for safe use.

The Blood Glucose / Cholesterol Monitoring System provides you with accurate, plasma-calibrated results based on electrochemical sense technology and the superior capillary sampling. The Blood Glucose / Cholesterol Monitoring System require only a small amount of blood, the result is precisely calculated and displayed.

Please read the entire "User's Manual" carefully before using the Blood Glucose / Cholesterol Monitoring System. The "User's Manual" guides you through the operation procedures with illustrated directions and help you find the required informations.

Please contact the local distributor for questions and enquiries.

WARNING:
Please carefully read the instructions in this "User's Manual" and become familiar with the test procedures before using the system. User should do the quality check and consult with a healthcare professional before doing any important medical decision.

1.2 Precautions

Please observe the following limitations for obtaining accurate results of Blood Glucose / Cholesterol Monitoring System.

- The measurements are only for reference purposes. For an analysis of the measurements, consult specialists.
- For In-vitro diagnostic use only (External use only).
- Single use only, please do not reuse the test strip.
- Do not use this product for those who cannot express their opinions properly including infants or babies.

- Handle the strip with clean and dry hands; lancing site for the test should be cleaned and dried thoroughly.
- Do not perform the test while a cell phone is used beside; prevent the electronic signal interference.
- Oxygen concentration in air is low may cause the test inaccurate; there is no effect from altitude up to 10,000 feet above sea level.
- Medical therapy for intravenous injection, such as immunoglobulin preparations and peritoneal dialysis solutions, containing sugar compounds may cause higher test results.
- Hematocrit（Hct）range from 30-55% is acceptable. Hct less than 30% may cause elevated result. Hct above 55% may cause reduced glucose results versus a whole blood reference.
- Do not drop the product.
- Keep the lancets and lancing device out of the reach of the children.
- Keep the meter and test strips at room temperature (10-30℃).

1.3 Intended Use

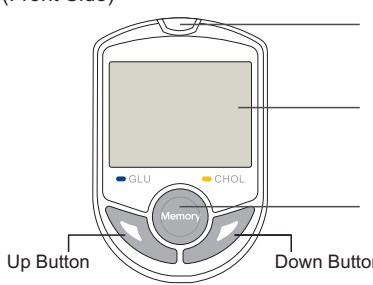
TBG-460GC Blood Glucose and Cholesterol Monitoring System is intended to be used for quantitative measurement of blood glucose level and cholesterol level in fresh capillary whole blood drawn from the fingertips. It is intended for use outside of body (In Vitro diagnostic use). It should be use only as an aid to monitor blood glucose and cholesterol level by individuals at home and by healthcare professionals at clinical settings.

1.4 Labelling and Informations

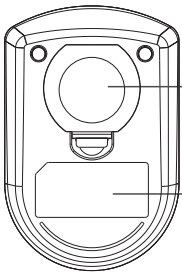
	Do not re-use		Read instructions
	Keep dry		Caution, consult accompanying documents
Operation 10°C 40°C	Operation temperature limitation	Storage 10°C 30°C	Storage temperature limitation
IVD	In-vitro diagnostic	EC REP	EU Representative
LOT	Lot number	REF	Catalogue number (Product number)
	Use by		Manufactured by
CE 0123	CE certification		

1.5 System Components

Meter (Front Side)



Meter (Back Side)



Battery Cover :
For holding a 3V lithium battery

Tag :
Display information about the meter.

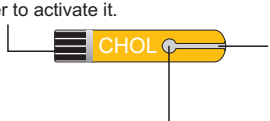
Glucose Test Strip (Blue Color)

Electronic Contact Bar :
Insert Electronic Contact Bar of the test strip into the Test Port of the meter to activate it.

Sample Inlet :
The inlet where the whole blood or control solution is drawn in. Touching a blood sample or control solution will result in a capillary action automatically

Cholesterol Test Strip(Yellow Color)

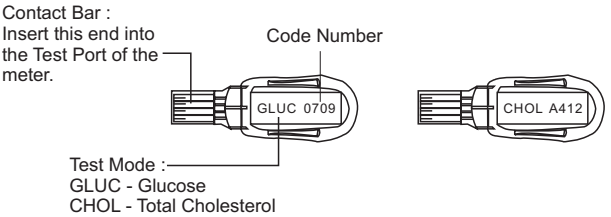
Electronic Contact Bar :
Insert Electronic Contact Bar of the test strip into the Test Port of the meter to activate it.



Sample Inlet :
The inlet where the whole blood or control solution is drawn in. Touching a blood sample or control solution will result in a capillary action automatically. At least 10uL of blood sample is essential.

Reaction Zone :
Reaction zone of Total Cholesterol

Code Strip (Front View)



Chapter 2 Setup the meter

2.1 Set the Year/ Month/ Day/ Hour/ Minute/ Measurement unit

Press and hold the “memory” button for over three seconds, the meter will sound one beep and enter the setting mode. Please follow the directions below to set the meter.
Under the setup mode, the LCD screen of the meter shows all setting items start from a blinking year “20XX” and the rest setting items are listed as follows:

Set the Year
1. When the meter enter setting mode, the first item on the screen such as “2012” will blink on screen, which means Year.
2. Press the up/ down button to until the correct year appears.
3. After you set the desired year number, Press the “memory” button again then the month segment starts blinking.

Set the Month
1. Press the up/ down button until the correct month appears.
2. Press the “memory” button, and then the day segment starts blinking.

Set the Day
1. Press up/dowm button until the correct day appears.
2. Press the “memory” button, and the hour segment will start blinking.

Set the Hour
1. Press up/ down button until the correct hour appears.
2. Press the “memory” button, and the minute segment will start blinking.

Set the Minute
1. Press up/ down button until the correct minute appears.
2. Press the “memory” button then measurement unit segment starts blinking.

1. Press the up/dowm button until the correct measurement unit appears.
2. Press the “memory" button will show "OFF" on the screen and power off.

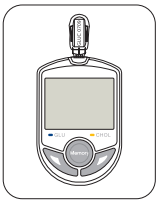
Chapter 3 How to perform Test

3.1 Before Testing

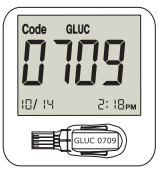
Coding the Meter

TBG-460GC meter should be coded before testing with test Strips for the first time, or every time a new box of test strips is used. Each vial of test strips has an assigned code number. The code strip is packaged with the test strip in order to calibrate/code the meter. Every time a test strip is inserted, please be sure to check the code number appearing on the screen is the same as the code number marked on the test strip vial.

Directions :



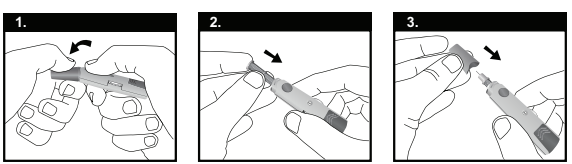
1. Insert code strip into the test port of the meter. Wait for the code number and test mode to appear on the screen.

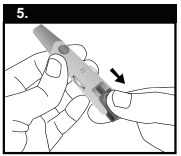


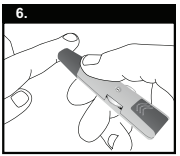
2. Make sure the code number on the screen is the same as the code number on the code strip, and the test mode is also the same as marked on the test vial. Remove the code strip. "☺" should appear on the screen, indicating that the meter has been successfully coded.

Cautions :
If "E-E" appears on the screen during coding procedure, there may be a problem with the code strip or a wrong category code strip may be misused. Perform the coding procedures again, and if "E-E" continues to appear, please contact the authorized distributor for service.

Use of Lancing Device







1. Remove the end cap by gently pushing it down and away from the lancing device.

2. Insert the lancet firmly into the lancet holder until it comes to a stop and remove the protective lancet cover.

3. Replace the end cap by snapping it back onto the lancing device body.

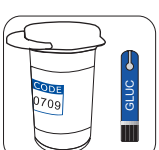
4. Select the skin penetration depth by turning the depth selector until the desired number can be seen in the selection window. 5 levels of skin penetration: The higher the number, the deeper it pricks.

5. Pull the part located at the back of the device until it comes to a stop and then release.

6. Place the lancing device firmly against the finger and press the release button to obtain a blood sample. After finishing your blood test, dispose the used lancet safely in an appropriate container.

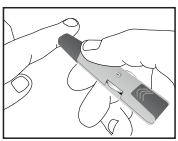
3.2 Perform the Blood Glucose Test

Directions :

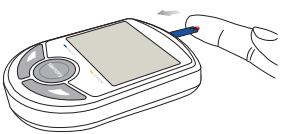


1. Insert a Blood Glucose test strip (blue color) into the test strip port of the meter and immediately cover the vial to keep the strips in dry condition. The meter will turn on automatically.

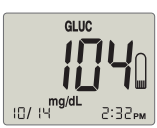
2. Be careful to make sure the test mode and code number on the screen are the same as the one marked on the test strip vial. Icon “GLUC” and “CHOL” indicate measuring mode of glucose and total cholesterol respectively. If not, remove the test strip and re-code the meter.



3. Obtain a drop of blood with a lancing device.
   Do not squeeze your fingertip hard to obtain a drop of blood. It may influence the result.



4. Touch the sample Inlet of the strip to the drop of blood sample until the meter sounds a “beep”, which means the sample has drawn into strip successfully.



5. The screen will display a count down from 10 seconds for glucose testing.

3.3 Perform the Total Cholesterol Test

1. Insert a Total Cholesterol test strip (yellow color) into the test strip port of the meter and follow the procedure as performing the blood glucose test.
2. Make sure to get enough blood sample volume.
3. The screen will display a count down from 26 seconds for cholesterol testing.

Note :
1. The TBG-460GC Monitoring System includes glucose and total cholesterol test that are all plasma calibrated. The user does not have to convert it into plasma result.
2. Use the strips before the expiry date, the strips can only be used within 3 months remaining shelf life after the first opening of the vial.
3. Apply the blood sample onto the correct position of the strip precisely, follow the directions to avoid incorrect operations.
4. Prohibited applying the blood sample to the test strip twice, it will cause inaccurate test results.

3.4 Special messages

Mode	Lo	Hi
Glucose	< 20 mg/dL (1.11 mmol/L)	> 600 mg/dL (33.3 mmol/L)
Total Cholesterol	< 100 mg/dL (2.59 mmol/L)	> 400 mg/dL (10.35 mmol/L)

3.5 Care after the Test

Directions:
1. Improper usage of the meter, such as dropping, bumping or other violent impact may cause the meter damaged.
2. Please keep meter away by interferences of magnetic, electromagnetic, and radioactive.

Warning :
1. Do not disassemble the meter for any reason.
2. Please follow local regulations to discard used test strips and lancets.
3. Used test strips, lancets and any other materials that have come in contact with blood should be treated as potential biohazards. If a user has an infectious disease, used test strips and other materials could be a sources of infection.

Chapter 4 Quality Control

Intended to use:
The control solution is used to check the performance of the system, including Blood Glucose and Cholesterol Monitor System, Glucose and Cholesterol strip, user's test skill. The system is performing adequately if the control solution test result falls within the indicated control range listed on the test strips vial label.

A control test should be proceeded:
1. When you suspect that the meter or test strips are not working properly.
2. When your blood glucose or cholesterol test results are not consistent with how you feel, or when you think your results are not accurate.
3. When you drop or bump your meter.
4. Upon the advice of the healthcare professional.

How to perform a control test.
1. Insert a test strip into the test strip port of the meter and immediately cover the vial to keep the strips in dry condition.
2. Be careful to make sure the test mode and code number on the screen are the same as the one marked on the test strip vial. If not, remove the test strip and re-code the meter to correct test mode and code number.
3. Shake the control Solution vial vigorously then open the cap to discard the first three drops of control solution, after wiping the dispense tip and cleaning with tissue then drop some control solution onto a clean object such as transparency. If it is a cholesterol test, Please drop out enough control solution (at least 10uL).
4. Touch the Sample Inlet of the Glucose or Cholesterol Test Strip to the drop of Control Solution until the Meter sounds a “beep”, The screen will display a count down from 10 seconds for Glucose Test Strip or 26 seconds for Cholesterol Test Strip.
5. After counting down, the Screen will display the control Test results, Compare the results to the control range listed on the Test Strip Vial.

Warning:

. Please read this user's manual for control solution test carefully before use.
. Do not reuse the Test Strips and close the Test Strip Vial lid tightly after use.
. The first three drops of Control Solution must be discarded and the vial should be shaked well before use when the vial is newly opened.
. Newly opened vial of Control Solution and Test Strips must be marked with the opening date.
. Glucose Control Solution is used for glucose test mode And Cholesterol Control Solution is used for cholesterol test mode.
. If the test results fall outside the control range, please reconfirm and repeat the test, if it is still fall outside the range, please contact authorized distributor for help and service.
. Control solutions are not included in the system, please contact your distributor if you want to do a quality control test.

Chapter 5 Meter Memory Function

TBG-460GC meter automatically stores up 360 blood glucose and 50 cholesterol test results. It also provides you with 7-, 14-, 21- and 28-day averages of the blood glucose test results. Please follow these directions to recall stored test results.

Directions :
1. Make sure that no test strip is inserted in the meter.
2. Press the “memory” button once to turn the meter on. After a short “beep” sound a full display will appear on screen then the meter enters standby mode.

Note :
The day average function can be applied to glucose test mode only, total cholesterol test mode do not have the day average function.

3. Press the “memory” button once again and the meter stays at memory mode. The 7-day average (7 DAY.A) will display on the screen.
4. Followed by 14, 21 and 28-day average when press the “memory” button repeatedly.

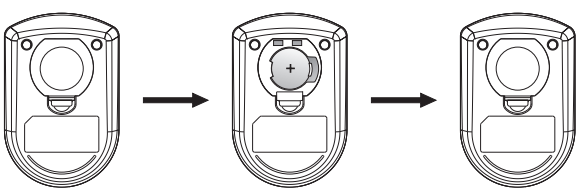
5. After the 28day-average, the latest stored result M01 appears on the screen. Then you can read the stored result from M01 to M360(Glucose mode) or from M01 to M50(Cholesterol mode) by pressing Down or UP Button.
6. Press the “memory” button for over 3 seconds and the meter will turn off after a long “beep” sound. Meter will also automatically shut down after 3 minutes without any operation.

Note :
If 360 test results are already stored and a new one is added, the oldest test result is automatically overwrited. The newest result will be shown in M01.

Chapter 6 Installing/Replacing the Batteries

Batteries
A 3V lithium battery (CR2032) is included in the meter package.
Use only 3V lithium batteries. Do not use or replace the battery with different types of batteries. Doing so will damage the electronics of the meter.

Instructions :



1. Hold the meter with one hand, slightly lift the back cover lid to open the back cover.
2. Insert a new battery in the meter with the "+" side facing up, you will hear a "beep" sound which indicates that meter is ready.
3. Place back the cover onto the meter.

Chapter 7 Storage and Handling of Meter and Strips

Due to sensitive to heat and humidity, the performance of test strips may be affected by improper storage and handling. Please store the test strips and meter carefully according to the specifications listed in chapter 8.

Note:

- Store the meter, code strip, test strips at room temperature. Do not expose them beyond the range described in Chapter 8.
- Do not freeze or refrigerate the meter and strips.
- Keep the meter clean by wiping the exterior of the meter with a tissue or lint-free cloth.

Chapter 8 Error Message and Trouble Shooting

Message	Cause	Solution
E-0	There will be a problem with the test strip.	Repeat the test with a new test strip. If the problem persists, please contact the dealer for service.
E-9	The test strip may be removed after applying blood the absorbent hole.	Revlew the instructiona and try again with a new test strip. If the problem persists, please contact the dealer for service.
E-b	The power of the battery is too low to run a test.	Replace the battery at once.
E-A	The reference voltage or other circuit is error.	Call local authorized distributor for help and service.

Message	Cause	Solution
E-E	1. There may be a problem with self-check of the meter. 2. Use of the wrong or damaged code strip or the code strip was inserted improperly.	Power off then retry, if the error appears again, contact the authorized distributor for service. Check that the code number on the meter display matches the code number on the test strip vial. Code the meter or retest as necessary. If the error message appears again, please contact the dealer for service.
E-t & Temperature Icon Sign	The temperature is below or above the system operating range.	Repeat the test after the meter and the test strip have reached at temperature within the operating range.
E-U	It could be caused by a used test strip or a temporary or permanent electronic problem.	Repeat the test with a new test strip. If the error message appears again, please contact the dealer for service.
HI	1. Blood glucose level is higher than 600 mg/dL. 2. Test strip has problem.	1. Review the instructions and try again with a new test strip. 2. Check the test strip vial to make sure that it is not marked beyond the expiration date.
Lo	1. Blood glucose level is lower than 20 mg/dL. 2. Test strip has problem.	1. Review the instructions and try again with a new test strip. 2. Check the test strip vial to make sure that it is not marked beyond the expiration date.

Chapter 9 Specification

System Accuracy	± 20% at Glucose level ⩾75 mg/dL (4.17mmol/L) ± 20% at Total Cholesterol ⩾150mg/dL(3.88mmol/L)
Principle	Electrochemical Biosensor
Calibration	Plasma-equivalent
Test Sample	Fresh Capillary whole blood
Measuring Time	About 10 seconds (Glucose), 26 seconds (Total Cholesterol)
Measuring Range	Glucose 20 - 600 mg/dL (1.1 - 33.3 mmol/L) Total Cholesterol 100 - 400 mg/dL (2.59 - 10.35 mmol/L)
Sample Volume	About 1 - 1.5 µL (Glucose) About 10 µL (Total Cholesterol)
Hematocrit Range	30 - 55% (for Glucose) 35 - 50% (for Total Cholesterol)
Strip Storage Condition	10 - 30ºC (50 - 86ºF)
Operation Temperature	10 - 40ºC (50 - 104ºF)
Relative Humidity	Less than 95%
Memory	360 for Glucose, 50 for Total Cholesterol
Battery Type	One 3V (CR2032) lithium battery
Battery Life	Approximately 1,000 tests
Dimensions	82*54*21.5mm (Length, Width, Height)
Weight	About 45 g (with battery)